



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,806	02/05/2004	Nikolaus Osterrieder	I/1199-1-C1	5527

28518 7590 01/24/2008

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY RD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
----------	--------------

1648

MAIL DATE	DELIVERY MODE
-----------	---------------

01/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,806	Applicant(s) OSTERRIEDER ET AL.	
	Examiner Benjamin P. Blumel	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2007 has been entered.

Claims 25-29 are examined on the merits. Claims 20-24 are still withdrawn from consideration based on the election without traverse of Invention I in the response filed on September 8, 2006.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 28 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 25. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection Necessitated by Amendments) Claims 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 26 and 29 both recite, “comprises essentially the entire genome...”, however it is unclear how much of the genome is actually present in the BAC since the specification defines “essentially” as the EHV genome is complete with the exception that it may have any type of mutation (see page 6, lines 10-15). Therefore, to what degree is the genome mutated? Claims 25, 27 and 28 are also indefinite since they depend from claim 26.

Claim 27 recites, “...characterized in that the EHV strain is lacking the glycoprotein gM”, however, it is unclear if this limitation is characterizing the deposited recombinant BAC of accession No. 01032704 or just indicates that the deposited BAC-EHV-1 has been further altered by deleting the gM protein.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(Prior Rejection Maintained) Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al. (Molecular Genetics and Metabolism, 2001) in view of Neubauer et al (Virology, 1997).

The instant invention is drawn to a polynucleotide encoding a bacterial artificial chromosome (BAC) accession No. ECACC 01032704, that comprises the essentially the entire genome of EHV-1 RacH that lacks glycoprotein M (gM). For purposes of examination, the claimed invention is interpreted to have mutations, which includes deleting all of the EHV-1 RacH strain genome with only one gene remaining based on the specification's definition of "Essentially" which means that the EHV genome is complete with the exception that it may carry any type of mutation as set out at p. 6, lines 10-15.

McGregor et al. reviews the discoveries of BAC as a tool to express the genome of numerous herpes viruses, such as HSV-1, which is an *Alphaherpesvirus*. One key feature of BAC is the ability to clone and express large sequences of up to 600kbp, for example, the 230kbp genome of murine cytomegalovirus, a betaherpesvirus. In addition, this property of BAC provides the ability to observe the effects of mutations on viral functions. Furthermore, McGregor et al. discusses therapeutic properties, which mutated viruses may possess with regard to virulence, immunogenicity and overall safety in vaccination of at risk populations. However, McGregor et al. do not teach the BAC of accession no. ECACC 01032704, which expresses EHV-1 RacH or a BAC that expresses a gM deficient EHV-1 RacH virus. *See pages 8-13.*

Neubauer et al. teaches comparing vaccination protection from EHV-1 challenge. A series of vaccinations were conducted on mice including wild type and mutant EHV-1 strains RacL11 and RacH. Each mutated strain contained an interruption of the gM or gB glycoprotein

gene with the LacZ gene. Mice (BALB/c) vaccinated with EHV-1 RacL11 or RacH mutants were shown to have protective immunity when challenged. For example, groups of mice were vaccinated with parental strains or with mutants thereof, 25 days later, RacL11 was administered to each group, bodyweight was monitored for the following 11 days. The bodyweight of the mock-infected mouse group decreased 20% by day 4. In addition, the viral loads from lung tissues of the negative control were 4.6×10^3 (avg.) as compared to 50 PFU/lung or less among pre-vaccinated groups. Furthermore, Neubauer et al. discuss potential success of EHV-1 RacL11 and RacH mutants, which do not express gM or gB, in providing protective immunity to equid subjects, especially an EHV-1 RacH strain that lacks gM as an effective but safe vaccine and expression vector. *See pages 36, 37, 41, 43, 44 and figure 4.*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by McGregor et al. in order to express related alphaherpesviruses in a BAC, thereby providing a BAC, which expresses a specific glycoprotein M deficient strain of EHV-1, such as RacH. One would have been motivated to do so, given the suggestion by McGregor et al. that the composition be used to express entire recombinant genomes of herpesviruses up to 600kbp. There would have been a reasonable expectation of success, given the knowledge that glycoprotein M and B deficient EHV-1 viruses maintain wild type life cycles and immunogenicity, as taught by Neubauer et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Summary

No claims are allowed.

Conclusion

Application/Control Number:
10/772,806
Art Unit: 1648

Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648